

The whys and hows of ISO 9001 certification

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Achieving certification requires an enterprise-wide effort, starting with commitment from top management.

The ISO 9000 standards were developed in 1987 by the International Organization for Standardization (ISO). They represent the common denominator of business quality which is accepted internationally. ISO 9000 certification demonstrates the capability of a supplier to control the processes that determine the acceptability of the product or service being supplied.

The ISO 9000 series involves four standards, ISO 9000 through ISO 9004. The four standards apply to different types of enterprises according to the scope of their activities.

The ISO 9001 standard confirms process conformance from the initial development of a product through production, test, installation, and servicing. ISO 9002 deals only with production and installation. ISO 9003 deals simply with final test and inspection. ISO 9004 is primarily a guidance document.

The ISO 9000 series (ISO 9001-9003) focuses on 20 aspects of a quality program which are subject to a rigorous audit during the certification process.

In 1988, the Commission of European Communities (EC) set a directive that companies in the chemical, pharmaceutical, food products, automotive, and other industries are required to have their quality systems registered and certified to the ISO 9000 standard by an accredited agency.

ISO 9000: Why is it important?

Certification will be a competitive requirement for business in post-1992 Europe. By mid-1990, there were more than 30,000 certified European companies. The numbers are growing dramatically as each nation brings on its own certification agencies and the deadline nears. In contrast, there are approximately 250 U.S. companies

which have achieved certification. Even if all the U.S. companies which do business in Europe were capable of being certified, there would be an insufficient number of accredited agencies recognized by the EC to handle the demand in time to meet the December 1992 target. Most of the accredited agencies are booked out a full year, and they are only handling the tip of the iceberg!

To compound the issue, even if a company is in good shape from a process quality standpoint, it will probably take an average of three to six months to do the necessary changes to manuals and systems. If its process quality isn't in good shape, depending on the company's size and scope, it can plan on a very rigorous year.

While conformance to the standard is not mandatory in the EC, one can expect that when a certified supplier is competing with a noncertified supplier, the certified one will be preferred.

Fourteen steps to certification

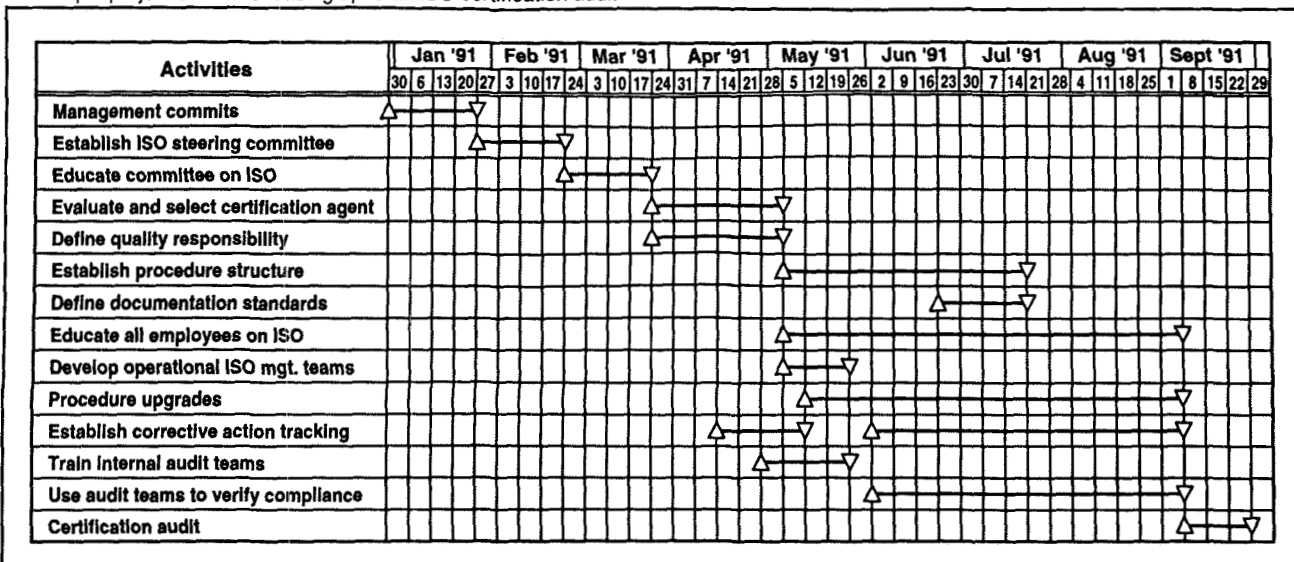
Qualifying for and receiving certification is an enterprise-wide endeavor. With management commitment and an existing quality infrastructure, it can take anywhere from three months to one year to mobilize all operations to ensure that the proper documents, procedures, and internal audits are in place. The sample project schedule shown in Fig. 1 is a guide to the events leading up to a certification audit.

Step 1: Obtain the commitment of senior management

The old adage that commitment must come from the top could never be more true. The senior management of the organization must commit to achieving ISO 9000 in the form of a firm determination that the company will achieve the objective, allocate the resources, and assign responsibility. ISO 9000 is an enterprise-wide standard that requires the shared commitment and involvement of all the executives within the senior management group and their respective operations.

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1. Sample project schedule leading up to an ISO certification audit

**Step 2: Establish an ISO steering council**

The primary charter of the council is to establish a comprehensive ISO development program and ensure its implementation with the proper allocation of resources. This group functions as the focal point for all the activities within the organization related to ISO 9000.

Step 3: Educate the council on ISO 9000

It is critical that the council members understand ISO 9000 and its elements in detail, as they will champion the effort in their respective organizations. It is also important that they develop a consensus among themselves as to what ISO 9000 is within their organization, and they need to share that among themselves. To assist in their efforts, questionnaires developed by the various certifying agencies can be used to assess organizational readiness. A commonly used one is the Underwriters Laboratory (UL) certification questionnaire. These questionnaires can act as an internal evaluation tool.

It is critical that this council be perceived as the experts within the company, as there will be many inquiries from the various organizations. In addition, it should be able to focus on the weaknesses within the organization and develop a series of strategies that will support their rapid improvement.

Step 4: Evaluate and select a certification agent

The evaluation and selection of a certification agent is critical. You must feel comfortable with each other. ISO 9000 is an interpretive standard which creates the opportunity for gray areas, so try to find a certification agent who understands your business. Get to know the probable lead auditor. Find out the auditor's interpretation of some of the questions that you might not be able to resolve.

When considering a certifying agent, ensure that it is a recognized registrar within the European Economic Community (EEC) scheme. Currently in the United States, there are two approaches being used. The most prevalent is the use of American certifying agents under the umbrella of an English certification agency, such as

the British Standards Institute (BSI). This relationship allows the company receiving the audit to receive a European/English mark recognized within the EEC. The other alternative is to go directly to a European accreditation agency, such as Det Norske Veritas (DNV), and receive the audit and certification directly from the European agency.

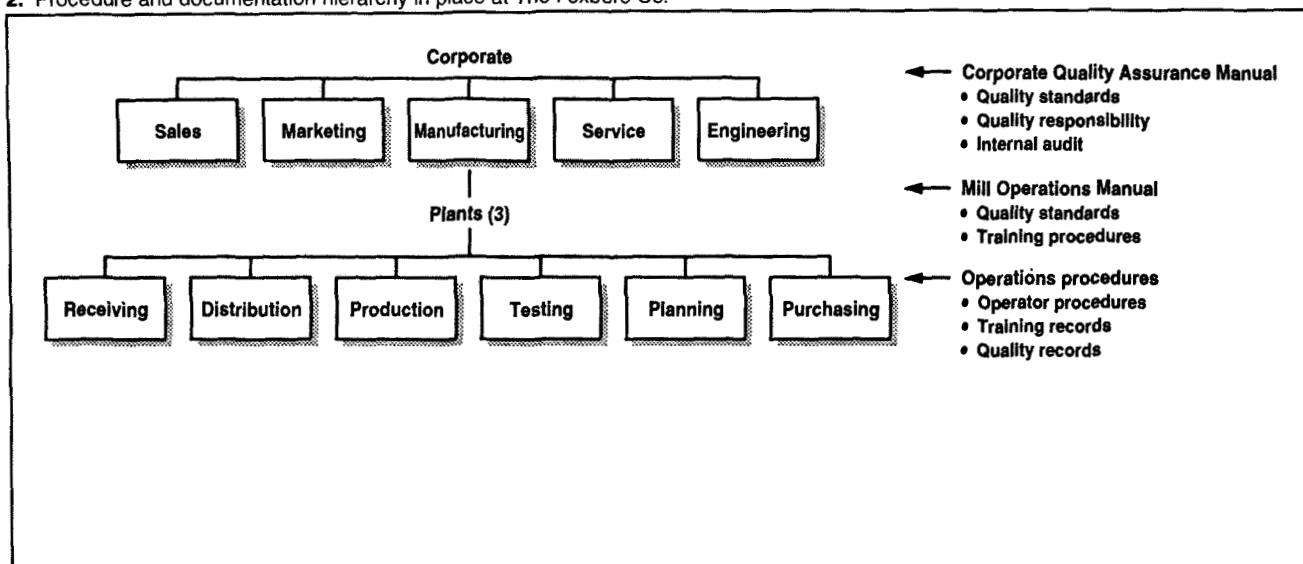
The European agencies, such as DNV, have now begun to establish offices directly in the United States to support this activity (DNV is located in Houston). Also, there are two different certification schemes: the English system, which is pass/fail at the time of the audit; and the Dutch system, which is a point scoring system. Both systems are very comprehensive and aggressive. While no comparison has been made between the two in terms of comprehensiveness, both encompass all the points of ISO 9000. It is reported that the Dutch scheme is more aggressive and requires a minimum score of 75% on all 400-plus inspection points to pass. To compensate for this aggressiveness, however, they do allow an organization to make corrections while the auditors are still on the premises. This system allows minor inconsistencies to be corrected quickly, which can prevent the need for a follow-up audit.

When negotiating a time frame for the audit, consider the possibility of not being successful at the first attempt. Negotiate a primary audit date and a follow-up audit date, as most agencies are booked far in advance. Failure to negotiate a follow-up date could result in an extended delay for the audit.

Step 5: Define quality responsibility

The ISO steering council should clearly define the responsibility for quality from the president through the entire organization. The definition of responsibility does not necessarily indicate that the individual has to be full-time and dedicated to quality; however, it does mean that the organization has to demonstrate that this individual has been actively involved in quality responsibility. This includes documented proof that there has been an activity associated with the defined responsibility.

2. Procedure and documentation hierarchy in place at The Foxboro Co.



Step 6: Establish procedure structure

It is likely that existing quality procedures will need to be restructured. Evaluate existing procedures for commonality and hierarchy. A strategy to consider is defining procedures in detail according to the organizational hierarchy they represent. By doing so, procedures will be relatively vague at the corporate level and only get into detail as required at the lower levels.

Figure 2 illustrates the procedure and documentation hierarchy in place at The Foxboro Co. Procedures are developed at each level. The top level procedures are general, with increasing detail at the operations level.

Companies could consider a structuring strategy that would include developing three layers of procedures. The first layer would consist of a corporate level that is relatively vague and primarily focused on the various standards that are being supported, how to approach ISO 9000 requirements, and the definition of the corporate quality assurance responsibilities. The second level would include plant level procedures in which the plant also defines its interpretation of ISO 9000, consistent with corporate quality assurance. Plant level procedures also define common elements which reflect the common elements within its organization. The third level, departmental operations, would be where detailed procedures, documents, and records are maintained. The majority of the detailed procedures would reside at this level.

Step 7: Define documentation standards

In this phase, as many of the documents as possible are standardized. Examples include corrective action reports, internal audits, procedures (in terms of appearance), and generally any common document. This process also takes a look at all the documents being used. Attempt to make one document serve as many purposes as possible.

Step 8: Educate all employees on ISO 9000

It takes a long time to get the message out. It is essential that everyone comprehend the meaning and requirements

of ISO 9000. Because ISO requires the full participation of all employees, it is important to reduce the resistance to this change, preferably through front-end education.

When employees understand the requirements and reason for change, they are less reluctant and do a better job. Through education, employees are mentally prepared for the very exhaustive preparation endeavor and audit. This preparation leads to confidence, which is apparent when they meet with the auditors.

Education also includes how to deal with the auditors and how to respond to their questions. The education process extends over several months and requires multiple communications before the general population understands what ISO is all about. During this time phase, continue to communicate the company's quality policy, as this will be part of the auditor's inquiry.

Step 9: Develop operational ISO management teams

With the education of the ISO council and the preparation of all the documents and standards, it becomes necessary to develop vehicles by which this information can be introduced into the organization so that the momentum can be established to execute the various elements of the program. This can be accomplished if each member of the ISO council goes into his or her organization and sets up operational units, usually by department, to install the ISO 9000 elements that are relevant to each group.

The council members act as resident experts. When questions arise that a council member does not feel comfortable answering alone, they are brought to the council as a whole. The council develops a position or contacts the lead auditor for a disposition. The ISO management teams should consist of senior members of the various organizations with key supervision out of each one of their groups.

The process should be managed on a weekly basis with the appropriate indicators in place to support visibility into the compliance process.

Step 10: Upgrade procedures

Procedure upgrades occur at all levels of the organization. They begin with management outlining the process flow and identifying the procedure documents and records requirements associated with that flow. The upgrade process includes looking at the existing procedures in place for upgrade, noting areas where there are no procedures, and developing new ones.

Step 11: Establish corrective action tracking

One of the required elements of ISO 9000 is the establishment of a corrective action process. The development of in-plant audit teams to gain visibility into the areas of noncompliance is a useful method. The findings of these teams can be documented with a quality corrective action request (QCAR). The QCAR becomes the primary method by which the strengths and weaknesses of the organization are identified. Tracking the QCAR status identifies how quickly weaknesses are remedied. This method provides confidence to move ahead with the ISO certification and ensures the ongoing compliance of the organization for follow-up visits by the ISO 9000 auditors.

Step 12: Train internal audit teams

The primary purpose of internal audit teams is to promote the self-auditing of an organization. Members from different parts of the organization are trained on the requirements of ISO 9000. They are joined with a certified lead auditor to create a plant miniaudit team. This team then reviews the organization, audits it, and initiates QCARs whenever there is a finding.

This same audit team can also support a supplier alliance program, applying ISO 9000 standards to suppliers. These audit teams also assist the ISO 9000 auditors in obtaining the answers to questions that arise. One of the many problems that an incoming auditor will have is speaking the language of the organization being visited. These internal plant miniaudit team members can speak a common language and act as interpreters for the auditors. This is critical to ensure that the proper messages are being communicated and to reduce the actual stress between the groups.

Step 13: Use corporate audit team to verify compliance

ISO requires there be a formal review of the organization and its compliance to the procedures. This requirement can be addressed through a corporate quality assurance audit team. This standalone team is a high visibility organization. This group sweeps behind the plant miniaudit teams to verify that the teams find all the issues and that they are being corrected. Using the miniaudit teams and the corporate audit teams ensures a high degree of visibility and confidence.

When the auditors arrive, they may visit the corporate audit teams first and review the audits of the past year. What they look for are any open findings that have not been closed by the plants or operations. In addition, they also look at the records for repeated problems. It is absolutely critical that all the open corporate findings be closed.

Step 14: Conduct the certification audit

The certifying audit is rigorous and comprehensive. It can take from one to three weeks to complete. A dedicated office area should be set aside for the auditors' use during their stay. It should include copies of all the relevant documents they will require.

The steering committee members escort the auditors and assist them with the location of operations and documents. Additionally, the steering committee should meet daily during the audit to review the previous day's results and implement plans to correct any findings prior to the conclusion of the audit.

The key is to promote a very open and friendly atmosphere. The auditors want you to succeed. On the other hand, they have their reputation to protect and the possibility of losing their certification is very real.

Achieving certification after the first audit is a major accomplishment. The effort that goes into the first audit must be sustained, as the auditors will return every six months to perform another less comprehensive but more rigorous audit on a specific operation. Passing these regular audits ensures continued ISO 9000 certification.

ISO 9000 and total quality

ISO 9000 certification should be considered a benchmark for evaluating the effectiveness of an organization's total quality management program. Total quality is a philosophy, woven into the fabric of a firm, which has customer satisfaction and continuous improvement at its foundation.

Pursuing certification is an excellent quality alignment tool. It drives procedural alignment among all organizations and contributes to the continuous improvement philosophy.

Benefits of certification

The updating and consistency of procedures provoked by the pursuit of certification can lead to millions of dollars in savings. Additional benefits of certification include:

- Fewer supplier audits
- Improved customer relations
- Access to European markets
- Competitive advantage
- Reinforcement of quality focus
- More efficient training
- Improved productivity.

ISO certification, coupled with a total quality management program, makes good business sense for the paper industry and its customers. □

Received for review July 15, 1991.

Accepted Dec. 11, 1991.

Presented at the TAPPI 1991 Process and Product Quality Symposium.

Keywords: Auditing, certification, EEC, international relations, ISO, organizations, procedures, quality, standards, USA.